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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/591,752

09/26/2006

Akiho Yokota

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06/03/2010

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EXAMINER

PAGE, BRENT T

ART UNIT

PAPER NUMBER

1638

NOTIFICATION DATE

DELIVERY MODE

06/03/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/591,752	Applicant(s) YOKOTA ET AL.	
	Examiner BRENT PAGE	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 6-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 6-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Reply filed by Applicants on 02/03/2010 is hereby acknowledged. The addition of New Claims 18 and 19 is hereby acknowledged. The DECLARATION of Akiho Yokota, submitted 02/03/2010 is hereby acknowledged. Claims 1 and 6-19 are pending and examined herein on the merits.

Claim Rejections - 35 USC § 112-2nd paragraph

Applicant's arguments, see page 5 of the response, filed 02/03/2010, with respect to indefiniteness have been fully considered and are persuasive when taken together with the claim amendments. The rejection of claims 16-17 under 35 USC 112 2nd paragraph for being indefinite has been withdrawn.

Claim Rejections - 35 USC § 103

Claims 1 and 6-17 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Yokota et al (EP1036842, provided by Applicant, published 9/20/2000), in view of Maliga et al (US Patent 5877402), in view of Palatnik et al (US patent 6781034, filed 10/24/2001) and further, in view of Gegenbach et al (US Patent 6146867).

The claims are drawn to a vector comprising a gene encoding a protein having FBPase and/or SBPase activities between a Rubisco large subunit gene and an acetyl CoA carboxylase subunit gene, wherein the gene encoding a protein having at least FBPase activity wherein the protein has at least 60% or more homology to SEQ ID NO:

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5, or wherein the nucleic acid encoding the protein has at least 60% homology to SEQ ID NO:6, wherein the vector has a ribosome-binding site upstream of a translation initiation point and a terminator downstream, wherein Rubisco and acetyl Co-A carboxylase are derived from tobacco, a recombinant gene vector comprising said vector, a transformed chloroplast comprising said vector and a plant comprising said chloroplasts.

Yokota et al teach the transformation of tobacco with a construct comprising a gene encoding cyanobacterial fructose-1, 6-bisphosphatase/sedoheptulose-1,7 bisphosphatase, for expression in the chloroplasts of tobacco, wherein the nucleic acid sequence for encoding cyanobacterial fructose-1, 6-bisphosphatase/sedoheptulose-1,7 bisphosphatase is 100% identical to SEQ ID NO:6 and encodes SEQ ID NO:5 of the present invention, wherein a terminator is located downstream of the translation initiation site (see figure 1 for example) and wherein the resultant peptide is targeted to the chloroplast and wherein photosynthesis is increased 1.74 times relative to non-transformed plants (see pages 1-4 of the specification, particularly lines 54-56 of page 2 relating to targeting the protein to the chloroplasts and lines 10-14 of page 4 relating to the increased photosynthesis).

Yokota et al do not teach a ribosome binding site upstream of the translation initiation site, nor does Yokota et al teach Rubisco and Acetyl Co-A carboxylase encoding DNA sequences as part of the transformation vector.

Maliga et al teach the transformation of tobacco chloroplasts with a gene of interest located between the large subunit of Rubisco and Acetyl-CoA carboxylase, with

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a ribosome binding site upstream and a terminator downstream, wherein the ribosome binding site and terminator is from tobacco (see claims 1-6, wherein the *rbcl* gene encodes the large subunit of Rubisco and the *accD* gene encodes Acetyl-CoA carboxylase, as understood in the art, and also 9th paragraph under “Summary of Invention” where it states “The 5’ untranslated region comprises a DNA sequence that encodes a ribosome binding site”, and Figures, for the constructs including the engineered 3’ end terminators). Maliga et al also teach that the transformation of chloroplasts using their method increases protein production and activity (see 3rd paragraph under “Discussion” for example).

Given the state of the art, the disclosures by Maliga et al and Yokota et al, it would have been obvious to one of ordinary skill in the art to use the method taught by Maliga et al to target the transformation of the cyanobacterial fructose-1, 6-bisphosphatase/sedoheptulose-1,7 bisphosphatase taught by Yokota et al to chloroplasts to increase photosynthesis with greater efficiency as suggested by Maliga et al. All of the claimed vector elements are taught by Maliga et al. The gene of interest and the effect of photosynthesis is taught by Yokota et al. It was known in the art at the time of filing that transforming chloroplasts as taught by Maluiga et al would increase the transcripts of the gene of interest which would be expected to increase the level of photosynthesis of the plant consistent with the findings of Yokota et al.

Response to Arguments

Applicant's arguments filed 02/03/2010 have been fully considered but they are not persuasive.

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Applicants urge that contrary to the instant invention, that the FBPase/SBPase gene-containing plasmid was purposely introduced into a tobacco nuclear genome and therefore one of ordinary skill in the art would not use the FBPase/SBPase gene taught by Yokota as the gene inserted between the Rubisco larg subunit gene and the acetyl CoA carboxylase subunit gene of Maliga to introduce the FBPase/SBPase gene into the chloroplast genome (see pages 5-6 of response).

This is not persuasive because as Applicants note, the FBPase/SBPase protein is ultimately localized to the chloroplast, even in Yokota and therefore would qualify as a "gene of interest" to be expressed in the chloroplast as taught by Maliga et al, but additionally, the teaching of Maliga et al that the construct of their invention increases protein production and activity sets forth both a motivation for using the construct of Maliga et al in expressing proteins in the chloroplast as well as a reasonable expectation of success in increasing the transcription and protein activity of a gene of interest. While Yokota et al do teach an increase in photosynthesis and localization to chloroplasts, the reference by Yokota et al primarily teaches the gene of the instant invention, providing evidence that neither the gene of the instant invention, nor the delivery vector or chloroplast expression are contributions over the prior art. The reference by Yokota et al does not teach away from expressing the FBPase/SBPase gene in chloroplasts, but instead, repeatedly refers to the incorporation or expression of FBPase/SBPase in the chloroplasts of the plant, indicating that contrary to teaching away, Yokota et al seems to suggest that the localization of FBPase/SBPase to the chloroplast is in fact desired. Therefore, the known system taught by Maliga would

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have been obvious to one of ordinary skill in the art as a useful means for insuring the localization of FBPase/SBPase in the chloroplast.

Applicants urge that the FBPase/SBPase gene-containing vector of the claimed invention is superior to that taught by Yokota and urge that this is a surprising and unexpected effect and urge the DECLARATION by Yokota shows the results of the comparison of the instant invention with that of Yokota et al in the prior art (see page 6 of response).

This is not persuasive because the suggestion by Maliga et al that protein expression and activity is increased in the chloroplast using their vector for a gene of interest suggests that increased photosynthesis and expression relative to a plant expressing the FBPase/SBPase gene in the nucleus would be expected and is consistent with the observations of Maliga et al. Applicants have not provided any evidence that either Yokota et al or Maliga et al teach away from the instant invention, or suggest that the increased levels of expression and thus photosynthesis would not have been expected by one of ordinary skill in the art.

The addition of claims 18 and 19 has necessitated the following new grounds of rejection.

Claim Rejections - 35 USC § 103

Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yokota et al (EP1036842, provided by Applicant, published 9/20/2000), in view of Maliga et al (US Patent 5877402), and in view of McBride et al (US Patent 6271444).

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The claims are drawn to a vector comprising a gene encoding a protein having FBPase and/or SBPase activities between a Rubisco large subunit gene and an acetyl CoA carboxylase subunit gene, wherein the gene encoding a protein having at least FBPase activity wherein the protein has at least 60% or more homology to SEQ ID NO: 5, or wherein the nucleic acid encoding the protein has at least 60% homology to SEQ ID NO:6, wherein the vector has a ribosome-binding site upstream of a translation initiation point and a terminator downstream, wherein the promoter is psbA and the terminator is rps16.

Yokota et al teach the transformation of tobacco with a construct comprising a gene encoding cyanobacterial fructose-1, 6-bisphosphatase/sedoheptulose-1,7 bisphosphatase, for expression in the chloroplasts of tobacco, wherein the nucleic acid sequence for encoding cyanobacterial fructose-1, 6-bisphosphatase/sedoheptulose-1,7 bisphosphatase is 100% identical to SEQ ID NO:6 and encodes SEQ ID NO:5 of the present invention, wherein a terminator is located downstream of the translation initiation site (see figure 1 for example) and wherein the resultant peptide is targeted to the chloroplast and wherein photosynthesis is increased 1.74 times relative to non-transformed plants (see pages 1-4 of the specification, particularly lines 54-56 of page 2 relating to targeting the protein to the chloroplasts and lines 10-14 of page 4 relating to the increased photosynthesis).

Yokota et al do not teach a ribosome binding site upstream of the translation initiation site, nor does Yokota et al teach Rubisco and Acetyl Co-A carboxylase encoding DNA sequences as part of the transformation vector.

Maliga et al teach the transformation of tobacco chloroplasts with a gene of interest located between the large subunit of Rubisco and Acetyl-CoA carboxylase, with a ribosome binding site upstream and a terminator downstream, wherein the ribosome binding site and terminator is from tobacco (see claims 1-6, wherein the *rbcl* gene encodes the large subunit of Rubisco and the *accD* gene encodes Acetyl-CoA carboxylase, as understood in the art, and also 9th paragraph under "Summary of Invention" where it states "The 5' untranslated region comprises a DNA sequence that encodes a ribosome binding site", and Figures, for the constructs including the engineered 3' end terminators). Maliga et al also teach that the transformation of chloroplasts using their method increases protein production and activity (see 3rd paragraph under "Discussion" for example).

McBride et al teach the transformation of plant plastids and teach that using the *psbA* promoter is common and a design choice (see 2nd paragraph under background of Invention, for example) and also teach the use of *rps 16* as a well-known terminator sequence (see Example 1, for example).

Given the state of the art, the disclosures by Maliga et al and Yokota et al, it would have been obvious to one of ordinary skill in the art to use the method taught by Maliga et al to target the transformation of the cyanobacterial fructose-1, 6-bisphosphatase/sedoheptulose-1,7 bisphosphatase taught by Yokota et al to chloroplasts to increase photosynthesis with greater efficiency as suggested by Maliga et al. All of the claimed vector elements are taught by Maliga et al. The gene of interest and the effect of photosynthesis is taught by Yokota et al. It was known in the art at the

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time of filing that transforming chloroplasts as taught by Maluiga et al would increase the transcripts of the gene of interest which would be expected to increase the level of photosynthesis of the plant consistent with the findings of Yokota et al. The use of the psbA promoter and rps 16 terminator are deemed design choices and the evidence supporting these as well-known design choices in the art particularly when transforming plastids is provided by McBride et al. One would have been motivated to use these vector components based on the successful transformation of plastids demonstrated by McBride et al.

No claims are free of the prior art.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRENT PAGE whose telephone number is (571)272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brent T Page

/Anne Marie Grunberg/

Supervisory Patent Examiner, Art Unit 1638